



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,894	08/24/2001	Richard T. Reel	5010-180	3333
7590	04/19/2005		EXAMINER	
Leonard D. Bowersox, Esquire KILYK & BOWERSOX, P.L.L.C. 3603-E Chain Bridge Road Fairfax, VA 22030			OLSEN, KAJ K	
			ART UNIT	PAPER NUMBER
			1753	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/938,894	REEL ET AL.
	Examiner	Art Unit
	Kaj K. Olsen	1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 18 January 2005.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 26-38 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 26-38 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. _____
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) 5) Notice of Informal Patent Application (PTO-152)
Paper No(s)/Mail Date. _____ 6) Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 26, 29, 30, 33, 34, 36 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Papp et al (USP 5,422,272).
3. With respect to new claim 26, Papp discloses an analyte manipulation device that comprises at least two coextensive electrically-conductive members (1, 2) disposed in fixed spaced relationship. See col. 3, ll. 31-41. Papp further discloses an AC power source adapted for electrical communication with the electrically conductive members for establishing an electric field gradient. See fig. 6 and col. 5, ll. 39-60. With respect to the electric field gradient being sufficient to retain a sample when the members are removed from a sample-holder, Papp teaches the application of 16,000 V/cm (i.e. 800 V with an interelectrode gap of 0.5 mm) (col. 6, ll. 17-22) or 3000 V/cm (see claim 24) with frequencies of 3000-5000 Hz (col. 4, l. 66 through col. 5, l. 3) or less than 10 kHz (see claim 24). According to the specification of the instant invention (p. 9, ll. 23-33); these power and frequency levels would be “sufficient to retain a sample when the members are removed from a sample holder”. Papp further discloses the presence of sample between the members. See col. 3, l. 64 through col. 4, l. 11. With respect to the sample being “retained by the electric field gradient”, this constitutes intended use. Applicant is not claiming a method of retaining a sample by electric field gradient, but an

apparatus for it. A prior art apparatus need only be capable of retaining the sample by electric field gradient. Based on the power and frequency levels disclosed by Papp (see above), Papp would be capable of meeting this limitation. Applicant must structurally define its apparatus away from the prior art in order to read free of a prior art apparatus. With respect to this retention being when "the members are outside of a sample holder", it would appear the applicant is attempting to claim the sensor at a particular moment in time. This particular moment in time would appear to constitute nothing more than the intended use. Any hypothetical patent containing claim 26 of the instant invention would presumably cover the applicant's apparatus with a sample between the members at all times regardless of whether the members are inside a sample holder or not (applicant isn't even claiming the sample holder itself), so it is unclear how a limitation about a particular moment in time can be utilized to differentiate the instant invention from the prior art. Because Papp discloses the coextensive members, AC power source and sample (as the examiner established above), it would meet the claim regardless of when the sample was between the two members. In addition, because Papp relies on positive pressure to expel the sample (col. 4, ll. 6-11), the sample of Papp would remain between the electrodes in absence of this positive pressure owing to capillary forces (i.e. interelectrode spacing is only 0.5 mm).

4. With respect to new claim 29 (those limitations not covered above), fig. 4 and 7 clearly show support structure that is moveable. The portion of the electrodes having sample would constitute an "end region" and a "concentration zone" giving the claim language its broadest reasonable interpretation.

5. With respect to new claim 30, the presence of resin material, see col. 3, ll. 60-64. A "hardenable adhesive" would appear to read on "resin" giving the claim language its broadest reasonable interpretation.
6. With respect to new claims 33 and 34, the conductive members of Papp have corners, edges, and points.
7. With respect to new claim 36, see col. 5, l. 61.
8. With respect to new claim 38, see col. 4, l. 60 through col. 5, l. 60.
9. Claims 26, 29, 33, 34 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Chang (USP 5,304,486).
10. With respect to new claim 26, Chang discloses an analyte-manipulation device that comprises two coextensive elongated electrically conductive members 25 disposed in a fixed space relation. Fig. 5a, 7b, 8b, 10a and 13c all read on the claimed elongate members. Chang further discloses the presence of an AC power source for electrical communication with the conductive members. See col. 7, ll. 59-66. Chang further discloses an electric field gradient that has voltages of 1-10 kV/cm and frequencies of 0.02 to 10 MHz. See col. 4, ll. 7-17. According to the specification of the instant invention (p. 9, ll. 23-33), these power and frequency levels would be "sufficient to retain a sample when the members are removed from a sample holder". Chang further discloses the presence of sample between the members. See fig. 1, 5B or 9 as an example. With respect to the sample being "retained by the electric field gradient", this constitutes intended use. Applicant is not claiming a method of retaining a sample by electric field gradient, but an apparatus for it. A prior art apparatus need only be capable of retaining the sample by electric field gradient. Based on the power and frequency levels disclosed by Chang

(see above), Chang would be capable of meeting this limitation. Applicant must structurally define its apparatus away from the prior art in order to read free of a prior art apparatus. With respect to this retention being when “the members are outside of a sample holder”, it would appear the applicant is attempting to claim the sensor at a particular moment in time. This particular moment in time would appear to constitute nothing more than the intended use. Any hypothetical patent containing claim 26 of the instant invention would presumably cover the applicant’s apparatus with a sample between the members at all times regardless of whether the members are inside a sample holder or not (applicant isn’t even claiming the sample holder itself), so it is unclear how a limitation about a particular moment in time can be utilized to differentiate the instant invention from the prior art. Because Chang discloses the coextensive members, AC power source and sample (as the examiner established above), it would meet the claim regardless of when the sample was between the two members.

11. With respect to new claim 29 (those limitations not covered above), said members are disposed in a manner that allows for movement between first and second positions both inside and outside of a holder 13 (compare fig. 5a with 5b).
12. With respect to new claims 33 and 34, the conductive members of Chang have corners, edges, points, bumps, protrusions, etc. See any of the above mentioned figures.
13. With respect to new claim 36, see col. 13, lines 10-12.
14. Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by Hoffman (USP 4,911,806). Changing the use of Hoffman from a 103 to a 102 rejection was necessitated by new claim 26 that doesn’t require a holder having first and second positions.

15. With respect to the claim, Hofmann discloses an analyte manipulation device for moving polarizable analyte of interest that comprises two coextensive, elongated, electrically-conductive members (14, 16) disposed in a fixed, spaced relation within a sample holder 18 (fig. 1, and col. 4, ll. 64-66). Hofmann also discloses an AC power source 26 in electrical communication with the members (col. 5, ll. 3-22). Hoffman establishes an electric field gradient with a strength of 200 V/cm with frequencies of 0.1 to 10 kHz. According to the specification of the instant invention (p. 9, ll. 23-33), these power and frequency levels would be "sufficient to retain a sample when the members are removed from a sample holder". Hoffman further discloses the presence of sample between the members. See col. 5, ll. 34-36. With respect to the sample being "retained by the electric field gradient" this constitutes the intended use. Applicant is not claiming a method of retaining a sample by electric field gradient, but an apparatus for it. A prior art apparatus need only be capable of retaining the sample by electric field gradient. Based on the power and frequency levels disclosed by Hofmann (see above), Hofmann would be capable of meeting this limitation. Applicant must structurally define its apparatus away from the prior art in order to read free of a prior art apparatus. With respect to this retention being when "the members are outside of a sample holder", it would appear the applicant is attempting to claim the sensor at a particular moment in time. This particular moment in time would appear to constitute nothing more than the intended use. Any hypothetical patent containing claim 26 of the instant invention would presumably cover the applicant's apparatus with a sample between the members at all times regardless of whether the members are inside a sample holder or not (applicant isn't even claiming the sample holder itself), so it is unclear how a limitation about a particular moment in time can be utilized to differentiate the instant invention from the prior art.

Because Hofmann discloses the coextensive members, AC power source and sample (as the examiner established above), it would meet the claim regardless of when the sample was between the two members. Furthermore, because Hofmann teaches that the device is for sorting and manipulating particles (see title and abstract) and because Hofmann relies on a narrow spacing which would produce capillary attraction (i.e. 0.5 cm interelectrode spacing before the copper wire is even wrapped around the electrode thereby reducing the spacing to below 0.5 cm (col. 5, ll. 24-28)), it is clearly capable of retaining sample if the members were removed from the sample holder.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1753

18. Claims 27-29, 33, 34 and 36 (and claim 26 in the alternative) are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann in view of Dahms (USP 4,124,470).

19. With respect to claims 27 and 29 (those limitations not discussed above for claim 26), Hofmann discloses all the limitations of the claims, but did not explicitly disclose the presence of a control unit for controlling the position of the members or a moveable support. However, configuring a analyte manipulation device such that it could be movable (i.e. that it can pulled in and out of a particular analyte container) is notoriously well known in the art. In particular, Dahms discloses in an alternate separation device that structure for the manipulation of a particular sample may be configured such that the said structure is useable on a plurality of different sample containing vessels thereby facilitating automated analyzing (fig. 2-4 and abstract). Said structure must be adapted so that it can be moved from first and second positions (i.e. it must be raised and lowered into and out of the vessel currently being analyzed) via motors (col. 9, lines 17-20). Alternatively, the turntable of Dahm (indicated by the arrows of fig. 3 and 6) moves the analyte holders through different positions such that the different analyte holders can be aligned with the said structure. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the structure of Dahms for the device of Hofmann in order to allow a particular analyte structure to be useable for a plurality of different sample holders and to automate the analysis of the analyte.

20. With respect to claim 28, the turntable of Dahms moves the analyte holder toward and away from the manipulating structure (which in Hofmann are electrically conducting members).

21. With respect to claims 33 and 34, the electrically conducting members of Hofmann inherently possesses edges or corners.

22. With respect to claim 36, an innumerable number of features of either Hofmann or Dahms could reasonably be utilized to function as a handle for holding the device.

23. With respect to claim 26 in the alternative, if applicant's limitations about the members being "outside of a sample holder" (the sample holder is unclaimed) were interpreted to require the members to be configured to move outside of a unclaimed sample holder, then claim 26 would be obvious in view of Dahms for the reasons set forth for claims 27 and 29.

24. Claims 29, 33, 34 and 36 (and claim 26 in the alternative) are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann in view of either Papp or Chang.

25. With respect to claim 29, Hofmann set forth all the limitations of the claims (see rejection above for claim 26), but did not explicitly disclose making the device adaptable for relative movement. However, Papp and Chang disclose devices for manipulating analyte in containers and teach making those devices movable in and out of a container. See the rejections above with Papp or Chang. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the movable teaching of either Papp or Chang for the device of Hofmann in order to allow a particular analyte structure to be useable for a plurality of different sample holders, thereby increasing device flexibility. In addition, making the device movable would permit the ability to clean, sterilize and/or repair the device thereby extending the operable lifetime of the device.

26. With respect to claims 33, 34, and 36, see the previous discussion of Hofmann and these claims.

27. With respect to claim 26 in the alternative, if applicant's limitations about the members being "outside of a sample holder" (the sample holder is unclaimed) were interpreted to require

the members to be configured to move outside of a unclaimed sample holder, then claim 26 would be obvious in view of Papp or Chang for the reasons set forth for claim 29.

28. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Papp or Chang in view of Dahms.

29. Papp and Chang set forth all the limitations of the claims, but did not explicitly recite the use of a control unit or holder-handling apparatus. However, it has been well established that merely automating previous manual operations requires only routine skill in the art. See *In re Venner*, 120 USPQ 192. This is particularly demonstrated by the previously discussed Dahms, which set forth such an automated device that allows for a particular analytical device to be inserted and removed from a given container (see rejection above). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Dahms for the devices of either Papp or Chang in order to automate the manipulation device.

30. Claims 30-32 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann and Dahms, Papp or Chang as applied to claim 29 above, and further in view of Goldstein (USP 4,643,814).

31. Claims 31, 32 and 35 (and claim 30 in the alternative) are rejected under 35 U.S.C. 103(a) as being unpatentable over Papp in view of Goldstein.

32. Claims 30-32 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang in view of Goldstein.

33. With respect to the claims, Papp, Chang or Hofmann in view of Dahms, Papp, or Chang disclosed all the limitations of the claims, but did not explicitly recite the presence of either resin material or non-conductive filament within the members. Goldstein teaches in an alternate

separation device teaches that materials can be placed between electrically conductive members to facilitate the holding of the desired analyte material (col. 4, line 53 through col. 5, line 38).

Among the materials contemplated include epoxy resin (col. 12, lines 5-10) and porous non-conductive filaments (e.g. see col. 4, lines 53-66). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Goldstein for the apparatus of any of Papp, Chang or Hofmann in view of Dahms, Papp or Chang in order to hold the materials that are being sorted, electroporated or fused.

34. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Papp or Chang in view of WO 00/49173 (hereafter "WO '173").

35. The references set forth all the limitations of the claim, but did not explicitly recite the presence of two or more pairs of conductive members per support. However, it has been well established that merely scaling up a particular analytical device requires only routine skill in the art. In particular, WO '173 demonstrates this in an alternate analyte manipulation device where a plurality of analyte manipulating electrodes 57 are mounting on a given support so that a plurality of different holders can be simultaneously analyzed. See fig. 13 and 14 in particular. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of WO '173 for the device of Papp or Chang in order to scale up a given manipulation device thereby increasing analyte manipulation throughput.

36. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann in view of Dahm, Papp or Chang as applied to claim 4 above, and further in view of WO 97/41219 (hereafter "WO '219").

37. The references set forth all the limitations of the claim, but did not explicitly recite the addition of a DC power source for the electrically conducting members. WO '219 teaches that the use of DC voltages allows one to capture DNA from an analyte solution thereby allowing said DNA to be removed from the solution and later replicated or amplified (p. 1, lines 15-24). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of WO '219 for the device of Hofmann in view of Dahm, Papp or Chang in order to capture the sorted DNA allowing said DNA to be replicated or amplified.

38. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chang.

39. Chang set forth all the limitations of the claim, but did not explicitly recite the use of a DC power source. However, Chang repeatedly disclosed that the use of DC was old in the art. See col. 2, lines 12-49. Hence, one possessing ordinary skill in the art would recognize that incorporating the use of a DC power source would increase the utility of the manipulation device for conventional DC cell fusion as well.

Response to Arguments

40. Applicant's arguments filed 1-18-2005 have been fully considered but they are not persuasive. Much of the applicant's argument concern why they believe the new claims with new limitations are free of the previous use of Papp, Chang and Hofmann. However, the examiner has addressed these new limitations and the interpretation of those limitations in the various rejections of claim 26. The examiner will not reiterate those arguments here. In short, these various limitations are merely *functional* language and do not explicitly define the instant invention *structurally* in a manner that reads free of the prior art.

41. Applicant's arguments concerning Hofmann in view of Dahms appear to be verbatim to arguments made in the appeal brief of 7-30-2004. The examiner addressed these various arguments in paragraphs 37 and 38 of the previous office action dated 10-19-2004 and will not reiterate those issues here. Furthermore, the examiner notes that applicant has traversed the combination of Hofmann and Dahms, but appears silent concerning the combination of Hofmann and either Papp or Chang.

42. Applicant's arguments concerning WO '219, Goldstein and WO '173 appear to rely on the applicant's perceived deficiencies of the primary teachings utilized. Because those arguments were not persuasive above, these rejections are also being maintained.

Conclusion

43. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Thursday from 5:30 A.M. to 3:00 P.M. and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AU 1753
April 15, 2005



KAJ K. OLSEN
PRIMARY EXAMINER